



**Luthra and Luthra**  
LAW OFFICES INDIA

**LIFESCIENCES AND HEALTHCARE NEWSLETTER**

*November 2025 Edition*



**INSIDE****Pharmaceuticals**

- **MoHFW published draft Notification regarding restriction of sale of drug products containing alcohol content**
- **Amendment under Drugs Rules to include more categories under Schedule H2**
- **Inclusion of additional items under CLAA in Drugs Rules 1945**
- **Rajasthan bans distribution of 19 medicines produced by Kaysons Pharma.**
- **Akums breaks ground in Zambia for new manufacturing plant**
- **UK pharma giant GSK secures global rights to preclinical ADC for advantage stage prostate cancer.**
- **Ahead of IPO, Rubicon Research collects Rs. 619 Cr from anchor investors.**

**Med-Tech**

- **Legal Metrology (Packaged Commodities) Rules, 2011 amended to align with Medical Device Rules, 2017**
- **Stempeucel becomes first India-developed cell therapy product to be licensed by a Japanese firm.**
- **MediSim VR launches Uttarakhand's first AI and VR medical simulation centre at HIMS**

**Healthcare and Hospitals**

- **Legal Metrology (Government Approved Test Centre) Rules, 2013 amended**
- **MoHFW revises CGHS rates with new accreditation- and city-based pricing**
- **ANRF, in collaboration with ICMR and Gates Foundation, launches Maha MedTech Mission**
- **Medanta signs MoU with Korean Association to enhance healthcare services**
- **Tripura Government signs MoU with AIIMS to develop centres of excellence in healthcare**

**Other Important Updates**

- **The NCB and the Rashtriya Raksha University Sign MoU to Boost Research and Training on Drug Crimes**
- **CCI clears Torrent's Pharma's proposal to buy stake in JB Chemicals**
- **30 pharma companies under MPFDA scrutiny**



## Pharmaceuticals

### LEGAL AND REGULATORY

#### **MoHFW published draft Notification regarding restriction of sale of drug products containing alcohol content**

A draft notification (**Notification**) to amend the Drugs Rules, 1945 was published on October 16, 2025 by Ministry Of Health And Family Welfare (**MoHFW**), The said Notification is to be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

Key amendments:

- **Schedule K (Serial no. 10):** The existing blanket exemption is modified so that oral formulations containing more than 12% alcohol v/v (Ethyl Alcohol) packed and sold in packing or bottles of more than 30 millilitres are no longer exempt from Chapter IV of the Act.
- **Schedule H1:** A new entry – All oral formulations containing more than 12% alcohol v/v (Ethyl Alcohol) packed and sold in packing or bottles of more than 30 millilitres – is added listing these formulations under Schedule H1, bringing them under stricter prescription and sale controls.

Source:

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTM1MjI=](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM1MjI=)

#### **Amendment under Drugs Rules to include more categories under Schedule H2**

MoHFW has published a draft notification (**Notification**) to further amend the Drugs Rules, 1945 on October 16, 2025. The said Notification is to be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

Key amendments:

The manner of labelling will now be applicable to Therapeutic Category of drug formulations which shall be listed under Schedule H2 in 'Table 2'. This Therapeutic Category of drug formulations include all Vaccines, Antimicrobials, Narcotic and Psychotropic drugs listed under the Narcotic and Psychotropic drugs Act, 1985, Anticancer drugs.

Source:

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTM1MTg=](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM1MTg=)

#### **Inclusion of additional items under CLA in Drugs Rules 1945**

MoHFW through a notification dated October 16, 2025 issued the draft Drugs (Amendment) Rules, 2025, (**Draft Rules**), under the Drugs and Cosmetics Act, 1940, proposed expanding regulatory oversight of



Central Licensing Authority (CLA) to include advanced biological and cellular therapies. The Draft Rules are to be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

The draft introduces key changes to the Drugs Rules, 1945 by adding Cell or Stem Cell–derived products, Gene therapeutic products, and Xenografts to several existing provisions that currently cover only Recombinant DNA (r-DNA)–derived drugs. These categories are inserted into Rule 75(3), substituted within Rule 75A (1A), and added across Rules 76 and 76A to ensure consistent regulatory treatment. These rules pertain to forms of application for licence to manufacture for sale or distribution of specific drugs and forms of loan licences to manufacture for sale or for distribution drug.

Additionally, Forms 27D, 27DA, 28D, and 28DA, used for manufacturing and licensing applications, are revised to reflect this expanded scope by replacing older terminology with broader coverage of Recombinant DNA (r-DNA) derived drugs/ Cell or Stem Cell derived products/ Gene therapeutic products or Xenografts, etc.

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTM1MTk=](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM1MTk=)

## **GOVERNMENT INITIATIVES**

### **Rajasthan bans distribution of 19 medicines produced by Kaysons Pharma.**

Rajasthan Medical and Health Department has taken strong regulatory measures after concerns arose about the safety of medicines supplied under its Free Medicine Scheme. The state government banned 19 drugs manufactured by Jaipur-based Kaysons Pharma and suspended the Drug Controller, Rajaram Sharma, following reports that a dextromethorphan-based cough syrup from the company was linked to child deaths and illnesses. Although earlier laboratory tests did not conclusively find the syrup defective, authorities cited the company's troubling compliance record, noting that over 10,000 product samples tested since 2012 included 42 that failed quality standards. In response, the government has established an expert committee to examine the company's products, quality control measures, and regulatory oversight. Updated safety advisories were also issued, including directives that dextromethorphan-based medicines should not be given to children under two years and that warnings on medicines potentially harmful to children or pregnant women be made clearer. The Health Minister emphasized that the ban is precautionary, with investigations ongoing to determine any definitive product faults.

#### **Source:**

[https://pharma.economictimes.indiatimes.com/news/pharma-industry/rajasthan-bans-distribution-of-19-kaysons-pharma-medicines-drug-controller-suspended/124303322?utm\\_source=category\\_listing&utm\\_medium=sectionListing](https://pharma.economictimes.indiatimes.com/news/pharma-industry/rajasthan-bans-distribution-of-19-kaysons-pharma-medicines-drug-controller-suspended/124303322?utm_source=category_listing&utm_medium=sectionListing)

## **INVESTMENTS**

### **Akums breaks ground in Zambia for new manufacturing plant**

Reportedly, Contract Development and Manufacturing Organization (CDMO), Akums Drugs and Pharmaceuticals has announced the initiation of construction of its first overseas manufacturing facility in



Zambia. The new facility is a Joint Venture (“JV”) with the Zambian Government to manufacture and supply medicines for the country's national health program.

Under the JV Akums will be a majority partner with 51% stakes, while a nominated Zambian state instrumentality will hold the remaining 49% stake. The new plant will be located at in the capital city of Lusaka at the Lusaka South Multi-Facility Economic Zone and will be constructed on approximately 40 acres of land. The facility is expected to be completed by 2028 and will look to manufacture general oral solids, liquids, and injectables, as well as beta-lactam products.

Zambian government has also committed to purchase medicines from the JV having a minimum aggregate value of \$50 million over 2 years in 2026 and 2027, i.e., USD 25 million annually, which will be manufactured and supplied from Akum's and/or its subsidiaries' facilities in India.

**Source:**

[https://pharma.economictimes.indiatimes.com/news/pharma-industry/akums-breaks-ground-in-zambia-for-new-manufacturing-plant/124869185?utm\\_source=category\\_listing&utm\\_medium=sectionListing](https://pharma.economictimes.indiatimes.com/news/pharma-industry/akums-breaks-ground-in-zambia-for-new-manufacturing-plant/124869185?utm_source=category_listing&utm_medium=sectionListing)

**UK pharma giant GSK secures global rights to preclinical ADC for advantage stage prostate cancer.**

GSK has secured exclusive global development and commercialization rights from Syndivia for a preclinical antibody-drug conjugate (ADC) targeting metastatic castration-resistant prostate cancer (mCRPC). The ADC is built using Syndivia's proprietary GeminiMab conjugation technology, and in preclinical trials it demonstrated strong anti-tumor activity and a favorable safety profile — shrinking tumors even at higher doses without a proportional increase in side effects. GSK sees this as a potential best-in-class asset that could address a currently underserved need, offering a more targeted therapy for mCRPC that could be deployed even in community-practice settings.

Financially, the deal includes an upfront payment plus success-based development and commercialization milestones, totalling up to 268 million Pounds, along with tiered royalties on future global sales for Syndivia. GSK will take full responsibility for developing, manufacturing, and launching the treatment.

**Source:**

<https://www.gsk.com/en-gb/media/press-releases/gsk-acquires-exclusive-rights-from-syndivia-for-antibody-drug-conjugate/>

**Ahead of IPO, Rubicon Research collects Rs. 619 Cr from anchor investors.**

It has been reported that, Rubicon Research, an Indian pharmaceutical firm, has raised Rs. 619 crores from anchor investors ahead of its IPO. It has allotted over 1.27 crores shares allotted to 32 institutional funds at Rs. 485 per share, including major domestic and global institutions like Goldman Sachs, HDFC Mutual Fund, Fidelity Funds, ICICI Prudential MF, and Kotak Mahindra MF among others. The upcoming IPO is sized at Rs. 1,377.5 crores, with Rs. 500 crores through fresh issue of equity shares and the remaining via an offer for sale by its promoter, General Atlantic Singapore RR Pvt. Ltd. After the IPO, General Atlantic's stake is expected to reduce over 35%. Proceeds from fresh issue (about Rs. 310 crores) will be used to repay debt and support inorganic growth and other corporate purposes.



Rubicon is a pharma formulations company with a strong emphasis on R&D and specialty products, especially in regulated markets like the U.S., where it earns nearly all its revenue. The IPO is set to open for public subscription on October 9, 2025, with a price band of Rs. 461–485 per share.

**Source:**

[https://pharma.economictimes.indiatimes.com/news/pharma-industry/rubicon-research-raises-rs-619-crore-from-anchor-investors-ahead-of-ipo/124416611?utm\\_source=category\\_listing&utm\\_medium=sectionListing](https://pharma.economictimes.indiatimes.com/news/pharma-industry/rubicon-research-raises-rs-619-crore-from-anchor-investors-ahead-of-ipo/124416611?utm_source=category_listing&utm_medium=sectionListing)

## Med-Tech

### LEGAL AND REGULATORY

#### **Legal Metrology (Packaged Commodities) Rules, 2011 amended to align with Medical Device Rules, 2017**

Department of Consumer Affairs, Ministry of Consumer Affairs, Food and Public Distribution amended the Legal Metrology (Packaged Commodities) Rules, 2011 vide notification dated October 23, 2025. These rules will be called the Legal Metrology (Packaged Commodities) Amendment Rules, 2025.

The key amendments are:

- In the principal display panel of the packages containing medical devices, the provisions of the Medical Devices Rules, 2017, shall be applied to make declarations.
- The provisions of the Medical Devices Rules, 2017, shall also be applied for the height and width of any numeral and letter to make declarations.
- Relaxations/exemptions provided in the Principal Rules will not apply to cases where the Medical Devices Rules, 2017 are applicable.

**Source:**

[https://consumeraffairs.gov.in/public/upload/files/267107\\_1761404707.pdf](https://consumeraffairs.gov.in/public/upload/files/267107_1761404707.pdf)

### INVESTMENTS

#### **Stempeucel becomes first India-developed cell therapy product to be licensed by a Japanese firm.**

According to reports, MEDINET Co., a Tokyo listed regenerative medicine and Contract Development and Manufacturing Organization (CDMO) has signed an option licence agreement with Stempeutics Research Pvt. Ltd., a Manipal Company to develop and commercialise Stempeucel product in Japan for treating Chronic Limb Threatening Ischemia (CLTI).

The agreement grants MEDINET the right to enter into exclusive license for Stempeucel. Under the deal, Stempeutics will receive an upfront payment and can be eligible for milestone payments, royalties and licensing fees if the option is exercised. Stempeucel manufacturing will continue at Stempeutics' facility in Bengaluru and exported to Japan for clinical trials and commercialisation. The companies have already initiated regulatory discussions with Japan's Pharmaceuticals and Medical Devices Agency (PMDA).



Stempeucel is the first India-developed cell therapy product to be licensed by a Japanese firm and patented in Japan. The product has received marketing approval from India's drug regulator Central Drugs Standard Control Organisation (CDSCO) for treating Critical Limb Ischemia cause by Buerger's Disease and Atherosclerotic Peripheral Arterial Disease.

**Source:**

[https://pharma.economictimes.indiatimes.com/news/pharma-industry/medinet-japan-stempeucel-india-ink-deal-for-stempeucel-cell-therapy-for-clti/124870575?utm\\_source=category\\_listing&utm\\_medium=sectionListing](https://pharma.economictimes.indiatimes.com/news/pharma-industry/medinet-japan-stempeucel-india-ink-deal-for-stempeucel-cell-therapy-for-clti/124870575?utm_source=category_listing&utm_medium=sectionListing)

### **MediSim VR launches Uttarakhand's first AI and VR medical simulation centre at HIMS**

MediSim VR has launched Uttarakhand's first AI- and VR-based Medical Simulation Centre at the Himalayan Institute of Medical Sciences (HIMS), Dehradun. The centre will be accessible not only to HIMS students but also to external medical learners and professional across Uttarakhand. The centre provides an immersive and highly interactive environment for medical students, nursing, and allied health professionals to enhance their training and professional development. Inaugurated during HIMS's annual SIMULUS event, the initiative was supported by Dr. Vinod K. Paul, Member of NITI Aayog, and highlighting government recognition of simulation-based medical training. The facility bridges the gap between theory and real-world practice. It represents a significant step in modernizing medical education in India and expanding access to advanced training technologies across the region.

**Source:**

<https://medicaldialogues.in/news/health/hospital-diagnostics/medisim-vr-launches-ai-and-vr-medical-simulation-centre-at-himalayan-institute-of-medical-sciences-156546>

## **Healthcare and Hospitals**

### **LEGAL AND REGULATORY**

#### **Legal Metrology (Government Approved Test Centre) Rules, 2013 amended**

Department of Consumer Affairs, Ministry of Consumer Affairs, Food And Public Distribution has amended the Legal Metrology (Government Approved Test Centre) Rules, 2013 vide notification dated October 23, 2025, these rules will be called the Legal Metrology (Government Approved Test Centre) Amendment Rules, 2025 (**Amended Rules**).

**Key amendments are:**

- Under Rule 3(1) weights and measures in the First Schedule can now be verified either by Government Approved Test Centres (GATC) or even legal metrology officers.
- Under Rule 5(1) for recognition of GATCs for carrying out verification of weights or measures, an application has to be submitted to Joint Secretary, Department of Consumer Affairs (instead of the Director of Legal Metrology as earlier) in the form specified in the Second Schedule.
- Under Rule 5, a new subrule 3A is inserted to provide that the Director or officers authorised by the Director of Legal Metrology to make considerations before approval of GATCs, can inspect the



premises of the test centre prior to making any recommendation for its approval, including the specification of its area of operation.

- Under Rule 5(16) all Regional Reference Standard Laboratories and National Test House Laboratories working under the Department of Consumer Affairs are now deemed GATCs and can verify weights and measures nationwide as per Legal Metrology (General) Rules, 2011 or the recommendations of the International Organization of Legal Metrology.
- Under Rule 7(1) the fee payable to test centre for verification or re-verification of weights or measures shall now be as specified in the Fifth Schedule: Provided that for the items not specified in the Fifth Schedule, the Legal Metrology (Enforcement) Rules of a State shall apply where Government Approved Test Centre is verifying the instrument.
- Under Rule 8, a new subrule is inserted to provide that the test centre shall now issue separate certificate of verification for each weight or measure, such that the certificate conforms to individual instrument.
- Under Rule 10, the place of verification of test centres is now extended to any part of the State in which the GATC operates.
- Under Rule 18 fees for applying to GATC has now been increased to two lakh per weight or measure, which shall be paid either by demand draft or online payment mode. The same amount of fee shall be payable at the time of renewal of recognition for a period of one year in respect of each equipment.
- First Schedule had been changed to include eighteen weights and measures which shall be verified by Government Approved Test Centre.
- In the Second Schedule, in the NOTE, for the letters and numbers Rs. 10,000/- the letters and words Rs. two lakh for one equipment per year has been added.
- In the Amended Rules, a new Schedule Fifth has been added to detail fee payable to Test Centre for verification or re-verification of weights and measures.

**Source:**

[https://consumeraffairs.gov.in/public/upload/files/267111\\_1761404639.pdf](https://consumeraffairs.gov.in/public/upload/files/267111_1761404639.pdf)

**MoHFW revises CGHS rates with new accreditation- and city-based pricing**

Ministry Of Health And Family Welfare (**MoHFW**) has updated the Central Government Health Scheme (**CGHS**) rates, effective October 13, 2025, introducing differentiated pricing based on accreditation status and location of healthcare facilities.

The new rates of CGHS differentiate accredited healthcare facilities, National Accreditation Board for Testing and Calibration Laboratories (**NABL**) / National Accreditation Board for Hospitals & Non-accredited facilities (Non-NABH and Non-NABL). Non-accredited healthcare facilities (Non-NABH/Non-NABL) will receive 15% lower rates compared to accredited healthcare facilities (NABH/NABL).



Healthcare organisations located in Y (Tier II) cities and Z (Tier III) cities rates shall be 10% and 20% respectively lower than those located in X (Tier I) Cities. Y (Tier II) rates also apply to the healthcare organisations located in North-East region and Union Territories of Jammu & Kashmir and Ladakh.

**Source:**

<https://nabl-india.org/wp-content/uploads/2025/10/NABL-accredited-Medical-laboratories.pdf>

## **GOVERNMENT INITIATIVES**

### **ANRF, in collaboration with ICMR and Gates Foundation, launches Maha MedTech Mission**

Anusandhan National Research Foundation (ANRF), in collaboration with the Indian Council of Medical Research (ICMR) and the Gates Foundation, has launched the Mission for Advancement in High-Impact Areas (MAHA)-Medical Technology.

The Mission will provide funding support to a wide range of entities including Academic and R&D institutions, Hospitals, Startups, MSMEs, MedTech industry and collaborations between entities. With milestone-linked funding of Rs. 5–25 crores per project (and up to Rs. 50 crores in exceptional cases), the Mission will support projects that bring impactful MedTech solutions to market. In addition to funding, the Mission will provide enabling support through national initiatives such as Patent Mitra (IP protection and technology transfer), MedTech Mitra (regulatory guidance and clearances), a Clinical Trial Network (for clinical validation and evidence generation), as well as mentorship from industry experts.

The scheme will cover a broad spectrum of innovative medical devices and in-vitro diagnostics, including equipment and key subcomponents, implants, assistive and surgical devices, consumables, and software-based medical solutions. The mission welcomes projects aligned with national health priorities such as tuberculosis, cancer, neonatal care, primary health care, etc.

Applications follow a two-stage process, with concept notes accepted from 15 September to 7 November 2025 and shortlisted applicants invited to submit full proposals from December 2025.

**Source:**

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2182432>

## **INVESTMENTS**

### **Medanta signs MoU with Korean Association to enhance healthcare services**

Reportedly, Medanta has signed a Memorandum of Understanding (MoU) for a two year partnership with the Korean Association in India to offer dedicated, high-quality healthcare services to Korean members of the association living in India. Under this agreement, Medanta will provide OPD consultations, executive preventive health check-ups, and inpatient care. To make things easier for the Korean community, they will set up a dedicated Korean helpdesk and helpline, staffed by a relationship manager to facilitate coordination and assistance. Members will also benefit from green-channel registration and VIP tagging for faster access. The partnership underlines Medanta's commitment to inclusive, culturally sensitive care and strengthens international cooperation in healthcare. Additionally, the MoU strengthens international cooperation in healthcare, fostering collaboration between Indian healthcare institutions and global communities.

**Source:**

<https://medicaldialogues.in/news/health/hospital-diagnostics/medanta-signs-mou-with-the-korean-association-to-enhance-healthcare-services-157022>

**Tripura Government signs MoU with AIIMS to develop centres of excellence in healthcare**

The Tripura government has signed a Memorandum of Understanding (MoU) with All India Institute of Medical Services (AIIMS) New Delhi to develop centres of excellence in healthcare across the state. This collaboration aims to strengthen Tripura's medical infrastructure and elevate existing institutions, particularly the Agartala Government Medical College and GB Pant Hospital, into modern, high-quality medical hubs aligned with international standards. Under the agreement, these hospitals will receive support to enhance both medical education and super-specialty care, transforming them into advanced healthcare centres, thereby improving access to high-quality treatment for residents of Tripura and neighbouring regions.

This initiative will significantly upgrade the state's healthcare ecosystem and expand specialized medical services that were previously limited. The MoU also emphasizes capacity building, skill development, and knowledge sharing between AIIMS experts and Tripura's medical staff, fostering a culture of excellence in patient care and research.

**Source:**

<https://medicaldialogues.in/news/health/hospital-diagnostics/tripura-govt-aiims-ink-mou-to-develop-centres-of-excellence-in-healthcare-157041>

**Other Important Updates****GOVERNMENT INITIATIVES****The NCB and the Rashtriya Raksha University Sign MoU to Boost Research and Training on Drug Crimes**

The Narcotics Control Bureau (NCB) and the Rashtriya Raksha University (RRU), today signed a Memorandum of Understanding (MoU) to enhance cooperation in the areas of research, training, technology development and capacity building related to narcotics control and cyber-enabled drug crimes. The MoU was signed by Director General, NCB, Anurag Garg, and Prof Bimal N. Patel, Vice Chancellor of RRU at a function in New Delhi. Under this MoU, the two institutions will collaborate to conduct joint research and innovation in emerging areas such as darknet narcotics markets, cryptocurrency tracing, and cyber-threat intelligence.

NCB and RRU will also work together to develop and deliver specialized training programmes on cyber forensics, blockchain forensics, OSINT, and behavioural profiling for NCB officers. Further, NCB and RRU will work towards establishing a Centre of Excellence in Cybercrime Investigation and Drug Intelligence as a hub for research and innovation.

**Source:**

<https://www.newsonair.gov.in/ncb-and-rru-sign-mou-to-boost-research-and-training-on-drug-crimes/>



## INVESTMENTS

### **CCI clears Torrent's Pharma's proposal to buy stake in JB Chemicals**

The Competition Commission of India (CCI) has approved Torrent Pharmaceuticals' proposed acquisition of a stake in JB Chemicals & Pharmaceuticals, at Rs. 19,500 crores, subject to certain voluntary modifications offered by the companies. Under the agreement, Torrent will acquire a 46.39% stake of JB Chemicals from its promoters, Tau Investment Holdings (an affiliate of KKR, a global investment firm) for about Rs. 11,917 crores, and then acquire 2.80% from employees for around Rs. 719 crores. After this, Torrent plans an open offer for 26% stake, in line with SEBI's listing norms, thus totalling to Rs. 6,842.8 crores

**Source:**

[https://pharma.economictimes.indiatimes.com/news/pharma-industry/cci-clears-torrent-pharmas-proposal-to-buy-stake-in-jb-chemicals/124731809?utm\\_source=category\\_listing&utm\\_medium=sectionListing](https://pharma.economictimes.indiatimes.com/news/pharma-industry/cci-clears-torrent-pharmas-proposal-to-buy-stake-in-jb-chemicals/124731809?utm_source=category_listing&utm_medium=sectionListing)

### **30 pharma companies under MPFDA scrutiny**

The Madhya Pradesh Food and Drug Administration (MPFDA) has put 30 pharmaceutical manufacturing firms under investigation following the tragic deaths of children in Chhindwara and Betul, which have been linked to toxic cough syrup. The inspection is focused on oral liquid drug manufacturers, including those producing syrups and suspensions and is being carried out jointly by MPFDA and the Central Drugs Standard Control Organisation (CDSCO). In the investigation, MPFDA has collected 243 samples of cough syrups and other oral formulations for testing. Preliminary results have declared at least three products, Coldrif, Respifresh TR, and Re Life, as substandard, and 1,086 bottles of these formulations have been seized to prevent further distribution.

In a proactive move, MPFDA has asked the Drug Controller General of India (DCGI) to make Diethylene Glycol (DEG) and Polyethylene Glycol (PEG) testing mandatory in all oral liquid drugs made in India, citing their known toxicity when contaminated.

**Source:**

<https://medicaldialogues.in/news/industry/pharma/30-pharma-firms-under-mpfda-cdco-scanner-in-madhya-pradesh-156864?utm>



*This newsletter is only for general informational purposes and shall not be construed to constitute legal advice (which can only be given after being formally engaged and familiarizing ourselves with all the relevant facts). Should you have any queries, or require any assistance or clarifications with regard to anything contained in this newsletter, please feel free to contact our partner, Mr. Pradnesh Warke.*

## The Team



**PRADNESH WARKE**  
 Partner  
 Email – [p.warke@luthra.com](mailto:p.warke@luthra.com)



**RAVI RAJ SHEKHAR**  
 Senior Associate  
 Email – [r.shekhar@luthra.com](mailto:r.shekhar@luthra.com)



**DEVASHREE KULKARNI**  
 Associate  
 Email – [dkulkarni@luthra.com](mailto:dkulkarni@luthra.com)



**TANAY JHA**  
 Associate  
 Email – [t.jha@luthra.com](mailto:t.jha@luthra.com)

## OFFICES



**NEW DELHI**  
 1st and 9th Floors, Ashoka Estate,  
 24 Barakhamba Road, New Delhi - 110 001  
 T: +91 11 4121 5100 F: +91 11 2372 3909  
 E: [delhi@luthra.com](mailto:delhi@luthra.com)



**MUMBAI**  
 20th Floor, Indiabulls Finance Center,  
 Tower 2 Unit A2, Elphinstone Road,  
 Senapati Bapat Marg, Mumbai - 400 013  
 T: +91 22 4354 7000  
 F: +91 22 6630 3700  
 E: [mumbai@luthra.com](mailto:mumbai@luthra.com)



**BENGALURU**  
 3rd Floor, Onyx Centre, No. 5, Museum Road,  
 Bengaluru - 560 001  
 T: +91 80 4112 2800 / +91 80 4165 9245  
 F: +91 80 4112 2332  
 E: [bengaluru@luthra.com](mailto:bengaluru@luthra.com)



**HYDERABAD**  
 Serene Towers,  
 House No. 8-2-623/A,  
 Road No. 10, Banjara Hills,  
 Hyderabad, Telangana - 500034  
 T: +91 40 7969 6162  
 E: [hyderabad@luthra.com](mailto:hyderabad@luthra.com)



**CHENNAI**  
 Prestige Palladium Bayan,  
 8th Floor, Greams Road, Nungambakkam Division,  
 Egmore, Chennai - 600 006,  
 Tamil Nadu  
 T: +91 95604 88155  
 E: [chennai@luthra.com](mailto:chennai@luthra.com)